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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/467,928      | 12/21/1999  | DAVID GAILLAC        | 017753-120          | 2965             |

21839 7590 07/30/2002

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EXAMINER

PARKIN, JEFFREY S

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1648

DATE MAILED: 07/30/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/467,928

Applicant(s)

GAILLAC, D., ET AL.

Examiner

Jeffrey S. Parkin, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 13-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_.

Detailed Office Action

*Status of the Claims*

1. Applicants' election with traverse of Group I (claims 1-12) in paper no. 7 is acknowledged. Applicants are advised that the restriction requirement set forth in paper no. 6 has been modified to more accurately reflect the claimed invention. This modification does not alter the elected group in any manner but more clearly identifies and explains the requirement and groupings as it pertains to Groups II and III. The restriction requirement should read as follows:

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- a. Group I, claim(s) 1-12, drawn to a method of inactivating enveloped viruses in a viral preparation employing various solvents, classified in class 435, subclass 238.
- b. Group II, claim(s) 13 and 14, drawn to a method for preparing a viral preparation comprising non-enveloped viruses, classified in class 435, subclass 239.
- c. Group III, claim(s) 15, drawn to a viral preparation comprising non-enveloped viruses, classified in class 435, subclass 235.

3. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, each of the identified groups is directed toward a different scientific objective (e.g, inactivating viruses in a preparation, preparing non-enveloped viruses) that employs different scientific reagents and methodology steps. Accordingly, each invention is clearly drawn toward a different inventive concept.

4. Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01).

5 In the instant case, the methodology of Group I neither requires nor uses the product of Group III. Moreover, the product of Group III neither requires nor uses the methodology of Group I. Therefore, the inventions are clearly directed toward different inventive concepts.

10 5. Inventions II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the  
15 product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case, the non-enveloped viral preparation can be prepared by a number of other materially different processes such as through recombinant gene expression techniques or physical agitation (i.e., sonication).  
20 Moreover, the claimed methodology can be employed in the preparation of materially different products such as inactivated enveloped and non-enveloped viruses. Accordingly, each invention is clearly drawn toward a different inventive concept.

25 6. Applicants traverse and submit that a serious burden is not present if the Examiner reviews all the claims concomitantly. This argument is not found to be persuasive for the reasons set forth *supra*. Moreover, applicants are reminded that establishment of *prima facie* evidence for a serious burden requires the  
30 demonstration, by appropriate explanation, of either separate classification, separate status in the art, or a different field of search as defined in M.P.E.P. § 808.02. As set forth *supra*, the

inventions display different classifications and a separate status in the art, generate unique issues regarding novelty, patentability, and enablement, and would require independent searches. Accordingly, the requirement is still deemed to be proper and is therefore made FINAL. Claims 13-15 are withdrawn from further consideration by the examiner, pursuant to 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

7. Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(I).

***Information Disclosure Statement***

8. The information disclosure statement filed 17 April, 2000, has been placed in the application file and the information referred to therein has been considered to the extent noted on the PTO-1449. Applicants are advised that document EP 0 812 858 A1 was not considered because an English translation was not provided. Concerning documents '420, '152, and '208, only the English Abstract was considered because an English translation of the text was not provided.

***35 U.S.C. § 112, Second Paragraph***

9. Claims 1-12 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Two separate requirements are set forth under this statute: (1) the claims must set forth the subject matter that

applicants regard as their invention; and (2) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant. The claims are directed toward a method of inactivating enveloped viruses in a composition comprising non-enveloped viruses which is vague and indefinite since the precise metes and bounds of the patent protection desired cannot be ascertained. For instance, it appears that the purpose of the methodology is to produce a composition that contains inactivated virus, regardless of the enveloped nature of the virus, since many of the claim limitations will also inactivate non-enveloped viruses as well. Alternatively, the claim language might be interpreted to mean that the composition is being manipulated in such a manner that enveloped viruses are inactivated while non-enveloped viruses remain active. Appropriate amendment of the claim language as supported by the disclosure is required (i.e, see page 5, first paragraph).

10. Moreover the claims are also vague and indefinite for reciting claim limitations employing the term "about". For instance, claim 1 contains the phrasees "about -5°C and +50°C" and "about 5 and about 9", which are vague and indefinite since the precise parameters of the claimed invention are not readily manifest. Appropriate correction is required.

**35 U.S.C. § 103(a)**

11. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner

in which the invention was made.

5 Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

10 12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of  
15 the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103© and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

20 13. Claims 1-12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kameyama et al. (1990). Kameyama and colleagues disclose methods for the inactivation of enveloped viruses that are contaminating a protein-containing composition by treating said  
25 compositions with 0.3% (w/v) TNBP and 1% (w/v) Tween 80 (see Examples 1 and 2, pp. 7 and 9, respectively). This procedure resulted in the inactivation of various enveloped viruses (e.g., VSV or Sindbis virus) without adversely affecting the infectivity of a non-enveloped virus (e.g., Echo virus). Various routine  
30 experimental parameters are also described (e.g., % of TNBP, % of detergent, temperature ranges, conductivity ranges, pH ranges, etc.). Although this teaching does not disclose the inactivation of enveloped viruses in a non-enveloped viral preparation, nevertheless, it would have been *prima facie* obvious to one having  
35 ordinary skill in the art at the time the invention was made to subject viral preparations to the aforementioned treatments, since

this would provide a means of ensuring the safety of non-enveloped viral vector preparations for any one of a number of purposes such as gene therapy or diagnostic applications. Moreover, Kameyama et al. (1990) state (p. 3, l. 13-25) that "There is no particular limitation posed on the protein-containing liquid composition to which the method of the present invention is applied. Examples thereof include plasma or tissue extracts, solutions comprising a fraction obtained by treating plasma or tissue extract by various fractionation methods, culture broths obtained by culturing a gene recombinant host or tissue and commercially available protein preparations (in a liquid form) or their solutions." Thus, both the motivation and a reasonable expectation of success were present in the prior art.

14. The following prior art, which was not relied upon in the office action, is considered germane to applicant's disclosure:

- Horowitz, B., et al., 1985, "Inactivation of viruses in labile blood derivatives. I. Disruption of lipid-enveloped viruses by tri (n-butyl) phosphate detergent combinations", Transfusion 25(6):516-22.

- Kameyama, S., et al., 1992, "Production method for protein-containing composition", U.S. Patent No. 5,151,499, filed 01/12/90.

- Stadler, M., et al., 2002, "A method for the inactivation of non-lipid-coated viruses", U.S. Patent No. 2002068355, filed 09/28/95.

### **Correspondence**

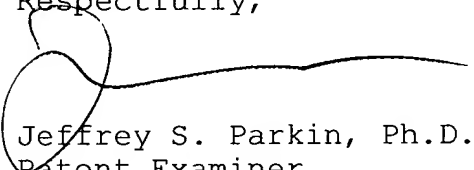
15. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242 or (703) 305-3014. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 308-4426. Applicants are encouraged to notify the



Examiner prior to the submission of such documents to facilitate their expeditious processing and entry.

- 5 16. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227. The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, James Housel or Laurie Scheiner, can be reached at (703) 308-4027 or (703) 308-1122, respectively. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.
- 10

Respectfully,



Jeffrey S. Parkin, Ph.D.  
Patent Examiner  
Art Unit 1648

27 July, 2002